UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

County of Lake, Ohio v. Purdue Pharma L.P., et al.,
Case No. 18-op-45032 (N.D. Ohio)

County of Trumbull, Ohio, v. Purdue Pharma L.P., et al.,
Case No. 18-op-45079 (N.D. Ohio)

"Track Three Cases"

MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

PHARMACY DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION FOR RECONSIDERATION OR CERTIFICATION

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SUMMARY OF ARGUMENT

Plaintiffs' Response confirms that reconsideration is warranted: The Court's finding that the Controlled Substances Act ("CSA") or DEA regulations promulgated under the CSA require pharmacy-registrants to aggregate and analyze their prescription records "to monitor for questionable prescriptions," Doc. 3403 at 15, imposes a new substantive rule of conduct that has not been duly enacted by Congress and that DEA has specifically declined to promulgate. Rather than address Pharmacy Defendants' legal authority and arguments, including the agency opinion rejecting the interpretation the Court has now adopted, Plaintiffs fall back on policy advocacy about how they would *like* DEA to regulate pharmacies. Pharmacy Defendants simply ask that the Court give effect to the CSA and DEA regulations as they are actually written. Arguments about what controlled-substance regulations *should* require of Pharmacy Defendants cannot change what the regulations *do* (and do *not*) require. Neither 21 C.F.R. § 1301.71(a) nor any other statutory or regulatory provision requires pharmacy-registrants to aggregate and analyze prescription records to hunt for "red flags" or to implement systems for monitoring controlled-substance prescriptions over and above the individualized judgment of licensed pharmacists. To the extent that Plaintiffs' public nuisance claims rely on this theory, they must be dismissed.

Plaintiffs do not seriously contest that these issues of statutory and regulatory interpretation "could materially affect the outcome of the case" and are therefore controlling. *In re City of Memphis*, 293 F.3d 345, 351 (6th Cir. 2002). The other preconditions for an interlocutory appeal are also satisfied. If the Court opts not to reconsider its Order, then it should certify the Order for interlocutory appeal. Plaintiffs offer no persuasive reason why the Court should not also reconsider its reliance on an inapplicable Ohio rule of construction to depart from

the plain meaning of an Ohio statute or, alternatively, certify that issue to the Ohio Supreme Court.

ARGUMENT

I. The Court Should Reconsider Its Order Denying the Motion to Dismiss or, at Minimum, Certify That Order for Interlocutory Appeal.

A. The Court's Holding That Pharmacy-Registrants Are Required to "Use" Their Prescription Records "to Monitor for Questionable Prescriptions" Is Based on Manifest Errors of Fact and Law.

Instead of engaging with the Court's holding, Plaintiffs try to raise it to a meaningless level of generality. According to Plaintiffs, the Order held merely "that the Pharmacy Defendants have duties under the CSA to provide effective controls against diversion." Doc. 3456 ("Resp.") at 2. That is not an accurate characterization. Rather, the Order held that "the CSA . . . imposes duties on the Pharmacy Defendants *to maintain systems*" to use their prescription records to monitor for "suspicious" controlled-substance prescriptions over and above the individualized judgment of their licensed pharmacists. Doc. 3403 at 21–22, 25 (emphasis added). Plaintiffs know this perfectly well, because it is the ruling they asked for, *see* Doc. 3366 at 14–15, apparently as an attempt to avoid the burden of proving actual dispensing violations, *see id.* at 21.[1] This ruling, as Pharmacy Defendants explained in their Motion, radically departs from the text of the CSA and its implementing regulations and from precedent governing how federal controlled-substance law applies to pharmacies.

[1] Plaintiffs also reprise the erroneous suggestion that rejecting this systemic data-based monitoring duty would mean that "the duties of the pharmacies are . . . limited . . . to guarding against theft," while leaving "diversion" unaddressed. Resp. 3. Pharmacy Defendants' Motion explained that this reasoning cannot be squared with the plain terms of 21 C.F.R. § 1301.71(a), *see* Doc. 3439 ("Mot.") at 12–13, and Plaintiffs offer no answer.

Plaintiffs do not cite any statute or regulation that expressly requires that pharmacy companies maintain systems to monitor for supposed suspicious prescriptions. Nor do they cite a single opinion—or even a single piece of DEA guidance—holding that the CSA implicitly requires as much. Nor do they deny that the Court's ruling upends pharmacy practice and the established legal rules that apply to every pharmacy—large or small, chain or independent, retail or hospital-based. *See* Doc. 3439 ("Mot.") at 5–6.

Nothing could better illustrate the problems with Plaintiffs' defense of the Order than their response to the new and unpredictable delays that may result if pharmacy-registrants must comply with new requirements to "check" each new prescription in real time against the records of past prescriptions before it can be filled. *See* Mot. 8. Plaintiffs have no answer other than to propose that "patients in severe pain" should simply go to a hospital to "receive medication directly from a treating physician," who could bypass the requirements that would newly govern the hospital pharmacy. Resp. 8. (Never mind the cost of an extra hospital visit, the long waits typical at busy emergency rooms, the burden of an extra trip to the hospital, or the risk of exposure to COVID-19—any patient suffering from acute pain who complains about this disruptive new regime, according to Plaintiffs, simply fails to "appreciate the importance of preventing diversion." *Id.*) For good reason, Congress delegated complex judgments about how to address the risk of criminal drug diversion while ensuring access to pain medication to a specialized agency. The agency may establish new binding legal obligations on registrants, but only if it first undertakes notice-and-comment procedures and considers input from all interested parties. A requirement that pharmacies maintain systems to use their records to monitor for suspicious prescriptions has not been duly promulgated—to the contrary, DEA has decided

against imposing such a requirement on pharmacy-registrants. Reconsideration is therefore needed.

1. The requirement that pharmacy-registrants keep certain records does not imply a separate, unstated legal obligation to "use" this "collect[ed] data."

Plaintiffs do not even attempt to defend the Court's statement that "the CSA *explicitly* requires pharmacies to . . . use [the prescription records they are required to collect] to monitor for questionable prescriptions that might lead to diversion." Doc. 3403 at 15 (emphasis in original). Such a requirement is not even *implicit*—much less explicit—in the CSA or in any DEA regulation. Pharmacy Defendants' Motion explained why the Court cannot properly infer from the fact that the CSA requires registrants to keep certain records the existence of a broad regulatory obligation to *use* those records to run algorithms to detect potential diversion. Mot. 9–12. Among other things, nothing in the CSA or DEA regulations requires pharmacy-registrants to maintain the required records in electronic (as opposed to paper) form, much less to filter the electronic data through computer algorithms as the Order suggests. *See id.* at 11, 14. The regulation relied on by the Court—21 C.F.R. § 1304.22(c)—does not even address, much less require, the prescriber-identifying records that the Order says must be monitored. *See* Mot. 11. And the CSA expressly specifies an altogether different purpose for maintaining the required records: review by federal law enforcement. *See id.* at 10; 21 U.S.C. § 827(b). Plaintiffs do not dispute any aspect of this explanation.

Instead, Plaintiffs try to pass off the Order as merely "not[ing] that the record-keeping requirements of the CSA give the Pharmacy Defendants tools for carrying out their obligations to protect against diversion" and "consider[ing] th[o]se other requirements in construing the scope of the obligation to provide effective controls against diversion." Resp. 3–4. But that is not what the Order said. In fact, the Court expressly relied on the recordkeeping requirements (which no

party had cited), *see* Doc. 3403 at 17, 25, to conclude that pharmacy-registrants are required by law to "use[] the data [they are] required to collect . . . to provide a tool otherwise unavailable to [their] pharmacists," *id.* at 24. Plaintiffs' revisionist account makes no sense, not least because prescription records (which may exist only in paper form, *see* Mot. 11) are not themselves "tools" sufficient for carrying out the Court's novel data-based obligation. As the Court itself recognized, the relevant tools would be computer algorithms, Doc. 3403 at 23 n.27—and nothing in the CSA or DEA regulations requires pharmacy-registrants to maintain such tools. *See* Mot. 14. By contrast, when DEA *has* required other types of registrants to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," it has done so explicitly. 21 C.F.R. § 1301.74(b). Likewise, when state regulators have chosen to implement prescription drug monitoring programs, such as the Ohio Automated Rx Reporting System—a "tool to track the dispensing . . . of controlled prescription drugs to patients . . . to monitor . . . for suspected abuse or diversion"[2]—they have also provided clear instructions to pharmacies regarding what information they must provide and how it should be aggregated.[3]

2. The "effective controls against diversion" regulation does not imply a duty to design and operate systems to monitor for "red flag" prescriptions.

Pharmacy Defendants' Motion explained why Section 1301.71(a)'s statement that "[a]ll . . . registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances" cannot provide a textual basis for the Court's conclusion. *See* Mot. 12–13. As the very next sentence of the regulation makes clear: "*In order to determine*

[2] Ohio Automated Rx Reporting System, *Welcome to OARRS*, https://www.ohiopmp.gov/ (last visited Sept. 15, 2020).

[3] *See, e.g.*, State of Ohio Board of Pharmacy, OARRS Data Submission Guide for Dispensers (June 2019), https://www.ohiopmp.gov/Documents/General/PHARMACIES_PRESCRIBERS/Ohio%20PMP%20Handbook%20(ASAP%204.2A)%20-%20Instructions%20for%20reporting%20dispensed%20drugs%20to%20OARRS.pdf (last visited Sept. 15, 2020).

whether a registrant has provided effective controls against diversion, the Administrator *shall* use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion." 21 C.F.R. § 1301.71(a) (emphasis added). And while those security requirements, as just noted, provide that manufacturer- and distributor-registrants "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances," *id.* § 1301.74(b), DEA elected not to make such a monitoring system a requirement for pharmacy-registrants, *see id.* §§ 1301.75–1301.76.

There is no evidence that this was an oversight; instead, it was a deliberate decision made by the agency charged with enforcing the CSA and maintaining the balance between protecting against diversion and ensuring patient access to prescription medications. Plaintiffs may disagree with DEA's decision not to include pharmacies alongside manufacturers and distributors when it imposed this systemic monitoring requirement, but that disagreement is no basis for the Court to reverse a policy determination that is squarely within the agency's purview. Plaintiffs have no response to any of this. Even as they acknowledge that "[i]t is necessary and required that an interpretation of a phrase . . . is not confined to a single sentence when the text of the whole [regulation] gives instruction as to its meaning," Resp. 4 (quoting *Maracich v. Spears*, 570 U.S. 48, 65 (2013)), Plaintiffs pretend that the phrase "[a]ll . . . registrants shall provide effective controls and procedures to guard against . . . diversion of controlled substances" exists in a vacuum, and that the next sentence of the regulation—defining the requirement—does not exist. The Order made the same manifest error of law.

Plaintiffs also do not attempt to address the DEA opinion holding that the "effective controls" regulation provides no basis to challenge dispensing practices. *See* Mot. 13 (discussing

Holiday opinion at Doc. 3379-1). And while Plaintiffs at least try to distinguish the recent district court decision holding that the regulation "does not require any specific security measures," *United States v. McKesson Corp.*, No. 19-CV-02233, 2020 WL 4805034, at *4 (N.D. Cal. Aug. 18, 2020), the meaning of the regulation does not depend on whether it is interpreted in a suit under the False Claims Act or in the context of any other cause of action.

3. "Agency decisions" do not require pharmacy-registrants to "identify red flags" through the analysis of prescription records.

A systemic monitoring requirement also cannot be derived from DEA enforcement proceedings and the use of the "red flag" concept within those adjudications. *See* Mot. 14–18. Plaintiffs cannot dispute that the CSA violation in each and every opinion they cite is the underlying actual dispensing by a pharmacist of illegitimate prescriptions with the requisite *scienter*, and not a pharmacy-registrant's failure to maintain a corporate-level system for checking prescriptions for red flags. *See* Resp. 4–5. Pharmacy Defendants' authority also shows that DEA's own experts define "red flags" as "*circumstances surrounding the presentation of a prescription to a pharmacist*," and not as signals within large datasets that can be discovered only through computer analysis. Mot. 17 (quoting *Holiday CVS, L.L.C.*, 77 Fed. Reg. 62,316-01, 62,332 (DEA Oct. 12, 2012) (emphasis added)). Plaintiffs simply ignore what this DEA precedent actually says, *see* Resp. 7, and then offer the circular observation that "what is recognizable to a human surely includes what a human can recognize with the assistance of a computer database." *Id.* The inescapable point, however, is that DEA decisions have never even suggested, much less required, that a pharmacy-registrant maintain a "global mechanism for reference to other prescriptions" to check for patterns potentially indicating improper prescribing, Doc. 3403 at 23.

Filling a prescription with knowledge that it lacks a legitimate medical purpose may be a basis for a CSA violation. *See* 21 C.F.R. § 1306.04(a) ("the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances"). But DEA has never said that corporate pharmacy-registrants (as opposed to their pharmacists) "are obligated to check for . . . red flags of possible diversion" before a pharmacist dispenses any controlled substance. Doc. 3403 at 22. It does not create "a corporate exception" to the rules, Resp. 6 (emphasis omitted), to recognize that no source of law requires *any* pharmacy-registrant (whether a sole proprietor or a chain pharmacy) to aggregate and analyze prescription records to search for "red flags" or to implement systems for monitoring controlled-substance prescriptions over and above the individualized judgment of licensed pharmacists.

Neither of the two sources Plaintiffs cite, *see* Resp. 5, supports their assertion that DEA has construed the CSA and its regulations to include the requirement that pharmacies—as opposed to pharmacists—check each and every controlled-substance prescription for signs of potential diversion. To the contrary, as Pharmacy Defendants have explained, *see* Doc. 3379 at 9–10 & n.10, both *United States v. Appalachian Regional Healthcare, Inc.*, 246 F. Supp. 3d 1184 (E.D. Ky. 2017), and *United Prescription Services, Inc.*, 72 Fed. Reg. 50,397-01 (DEA Aug. 31, 2007), stand for the unremarkable proposition that it is possible to establish that a corporate person (like any other person) knowingly participated in the filling of *particular illegitimate prescriptions*. Neither of these opinions (nor any other court decision, agency adjudication, or even agency guidance) suggests that a pharmacy-registrant violates the CSA if it does not act, independently of any pharmacist, to "check for . . . red flags of possible diversion" before dispensing. Mot. 14; *see also id.* 14–18.

Plaintiffs accuse Pharmacy Defendants of special pleading for corporations, Resp. 7, but it is Plaintiffs, not Pharmacy Defendants, who are seeking a corporate exception, by insisting that the *scienter* required for a dispensing violation can be imputed from the mere possession of prescription records. *Id.* at 6. Crucially, "a corporation 'knows' through its agents," not through the mere *possession* of records from which information *theoretically* could be gleaned. *United States v. One Parcel of Land*, 965 F.2d 311, 316 (7th Cir. 1992); *see also Holiday CVS*, 77 Fed. Reg. at 62,341 (citing *One Parcel of Land* and, in the context of the CSA, applying the principle that "[o]nly knowledge obtained by corporate employees acting with[in] the scope of their employment is imputed to the corporation"); *cf. Southland Sec. Corp. v. INSpire Ins. Sols., Inc.*, 365 F.3d 353, 366 (5th Cir. 2004) (when *scienter* is an element of a cause of action that also involves some sort of conduct, the corporation has the requisite *scienter* only if the individual corporate agent who engages in the relevant conduct possesses the requisite *scienter*). Plaintiffs are thus wrong as a matter of law to equate a corporation's possession of raw data with the corporation's "knowledge" of information that could be gleaned only by *analysis* of the aggregate data, regardless of whether any agent of the corporation has actually performed that analysis and obtained that knowledge. *See* Resp. 6–7.

4. Arguments about how DEA could or should regulate pharmacies are beside the point.

Finally, relying on a 2013 "perspective" article in the *New England Journal of Medicine*, Plaintiffs argue that chain pharmacies "are able to use" aggregated prescription data "to identify illegitimate prescribing patterns not readily apparent on the basis of an individual prescription." Resp. 6. This gets Plaintiffs nowhere, because the issue is not what sort of systems or procedures a pharmacy company has elected to implement *in its discretion* in an effort to combat opioid abuse. Nor is the issue what DEA *should* require pharmacy-registrants to use. The issue before

the Court is what the law actually does and does not require. As Pharmacy Defendants have explained, the Order improperly "substitut[es] [the Court's] own interstitial lawmaking for" Congress's and DEA's by announcing a legal requirement that not only cannot be found in the text of the CSA or any of its implementing regulations—but also that DEA has decided against imposing on pharmacy-registrants. Mot. 6–7 (quoting *Ford Motor Credit Co. v. Milhollin*, 444 U.S. 555, 568 & n.12 (1980)). Plaintiffs argue (incorrectly, *see supra* pp. 8–9) that the Court's holding is "the same requirement DEA has repeatedly imposed on individuals," Resp. 7, but ultimately they do not contest that DEA has never suggested, let alone provided notice of, the Court's newly created requirement that pharmacy-registrants design and maintain data-based systems to identify "suspicious" prescriptions, *see id.* at 6. Because this holding is clearly erroneous and reflects a wholesale change in law affecting the delivery of medicine to patients, the Court should grant reconsideration.

B. The Court Should Certify an Interlocutory Appeal to Address the Nature and Scope of Pharmacy Duties Under the CSA.

If the Court will not reconsider its Order, it should certify the Order for interlocutory appeal so that the Sixth Circuit can resolve the controlling and significant questions raised above about the scope of pharmacies' duties under the CSA. The Order satisfies all three conditions for interlocutory appeal under 28 U.S.C. § 1292(b): "[1] [it] involves a controlling question of law [as] to which there is [2] substantial ground for difference of opinion and . . . [3] an immediate appeal may materially advance the termination of the litigation." *In re Trump*, 874 F.3d 948, 951 (6th Cir. 2017) (emphasis omitted).

Plaintiffs do not dispute that the issues of statutory and regulatory interpretation addressed in Pharmacy Defendants' Motion are pure questions of law, and they do not seriously dispute that they are controlling in these cases. Plaintiffs argue that, even if the appeal were

decided in Pharmacy Defendants' favor, their absolute public nuisance claims "would still proceed on the basis that Defendants acted intentionally." Resp. 12. But a legal issue is controlling if it "could materially affect the outcome of the case." *In re City of Memphis*, 293 F.3d at 351. Plaintiffs do not deny that the outcome of the case would be materially affected if Plaintiffs were left with only an alternative theory of doubtful viability, both on its own terms and in light of the principles of conflict preemption. Under that alternative theory, as Pharmacy Defendants have explained and as Plaintiffs neglect to mention, Plaintiffs would have to establish a public nuisance based on conduct that was both intentional *and* culpable. Specifically, they would have to prove that a Pharmacy Defendant "intended to bring about the conditions which are in fact found to be a nuisance." *Nottke v. Norfolk S. Ry. Co.*, 264 F. Supp. 3d 859, 863 (N.D. Ohio 2017); *see* Doc. 3379 at 14.

Pharmacy Defendants' Motion explained that these controlling legal issues are questions of first impression on which fair-minded jurists could well reach a decision contrary to the Court's. Mot. 22–23 (citing *In re Trump*, 874 F.3d at 952). In response, Plaintiffs contend that "the text of § 1301.71(a), as well as a wealth of [unspecified] precedent supports the Court's conclusion." Resp. 12. As established above, Plaintiffs are incorrect: The text of Section 1301.71(a) does not and cannot support the novel data-monitoring obligation, nor does any precedent. To the contrary, the statutory and regulatory text, along with decades of agency practice, run directly contrary to the Court's conclusion. What is more, in square conflict with the Court's holding, another district court recently held that "Section 1301.71(a) does *not* require any specific security measures." *McKesson Corp.*, 2020 WL 4805034, at *4 (emphasis added). Plaintiffs seek to distinguish this as a False Claims Act case, *see* Resp. 5 n.1—but, as explained *supra* p. 7, that distinction gets them nowhere. The district court in that case held that the

relators failed to state a claim under the False Claims Act because they had "not adequately alleged that McKesson violated any regulations," given that the CSA security regulations—the very same regulations at issue here—"do not always require strict compliance," *McKesson*, 2020 WL 4805034, at *4 (citing 21 C.F.R. § 1301.71(b) ("[s]ubstantial compliance . . . may be deemed sufficient by [DEA])), and that DEA has "discretion to decide" whether a registrant has complied with Section 1301.71(a), *id.* *See also Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1327 (D.C. Cir. 1995) ("agencies, not courts, retain control over which permissible reading of the regulations they will enforce").

Finally, an immediate appeal will materially advance the ultimate termination of this litigation. Plaintiffs' only argument to the contrary is that "substantial discovery" has already occurred. While substantial discovery has been taken in Track 1, these Track 3 cases have been active for only a few months. More to the point, and undisputed by Plaintiffs: If the Court is wrong about the nature and scope of Pharmacy Defendants' obligations under the CSA, then the Track 3 bellwether will be of no value to the ultimate resolution of the MDL. It would turn entirely on the alleged violation of obligations that do not exist.

All preconditions to certification of an interlocutory appeal are therefore satisfied, and the Court should certify an appeal if it will not reconsider its Order.

II. The Court Should Reconsider Its Holding That the *Morris* Rule of Statutory Construction Applies to Ohio Rev. Code § 4729.35 and Its Refusal to Certify the Issue to the Ohio Supreme Court.

The meaning of Ohio Rev. Code § 4729.35 is plain, in light of the General Assembly's comprehensive scheme governing the distribution and dispensing of drugs of abuse: The sole remedy for a "public nuisance" based on an alleged violation of laws governing the distribution of drugs of abuse is injunctive relief. The General Assembly had no reason to declare that it was

abrogating the "common law" form of such claims because a public nuisance action premised on alleged violations of regulations governing drugs of abuse is not a recognized "common law" cause of action. Plaintiffs cite cases invoking *State ex rel. Morris v. Sullivan*, 90 N.E. 146 (Ohio 1909), to find that various settled common-law rules (such as the learned-intermediary doctrine, the rule that a landlord owes a tenant's guests the same duties as the landlord owes to the tenant, or the rule that a party has a right to cross-examine an adverse witness) that were not directly addressed by a given statute were not implicitly repealed. But they point to no precedent interpreting Ohio Rev. Code § 4729.35, or applying the *Morris* rule as the Order does here: to allow a plaintiff to seek remedies foreclosed by a statute that is *directly concerned* with the plaintiff's cause of action. The case that comes closest, *Carrel v. Allied Prods. Corp.*, 677 N.E.2d 795, 798 (Ohio 1997), was overturned by legislation. In short, as Pharmacy Defendants have explained, Ohio law is, at minimum, unsettled as to whether Ohio Rev. Code § 4729.35 forecloses Plaintiffs' public nuisance claim seeking inconsistent remedies.

Certification to the Ohio Supreme Court is appropriate here, where there is no controlling Ohio Supreme Court precedent and the question is determinative of Plaintiffs' public nuisance claim. Plaintiffs do not dispute that the question is determinative, and—as just explained—cases applying the *Morris* rule within that rule's domain are not "controlling precedent" on this question. Finally, Pharmacy Defendants timely asked the Court to certify the issue to the Ohio Supreme Court. *See* Doc. 3379 at 2 n.3. Pharmacy Defendants now respectfully ask the Court to reconsider its Order on this point or, if it will not do so, to certify this determinative issue implicating the meaning of an Ohio statute, the content of Ohio common law, and the scope of an Ohio principle of statutory construction to the Ohio Supreme Court.

CONCLUSION

The Court should grant Pharmacy Defendants' motion for reconsideration or certification of the Court's August 6, 2020 Order.

Dated: September 15, 2020

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record on September 15, 2020.

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